

REMARKS

Claims 15-24, and 26-30 are currently pending in this application. Claim 25 is hereby canceled. Claim 27 has been amended to correct an antecedent basis issue. Claims 1-14 were previously canceled in this application.

Rejections Under 35 U.S.C. § 103(a)

In the Office Action, the Examiner rejects independent claim 15, and dependent claims 16-30 under 35 U.S.C. § 103(a) as being unpatentable over Reiley (U.S. Publication No. 2003/0028250) in view of Zucherman (U.S. Patent No. 5,836,948).

Particularly, the Examiner states that Reiley discloses all of the features of the claimed invention including a spacer body having a top end face (36), lower end face (38), groove (42), openings in the groove, and a longitudinal housing extending orthogonally to the groove. The Examiner acknowledges, however, that Reiley does not disclose “a strap having a first end passed into the first opening and a second end passed into the second opening.” (Page 4 of the Office Action). The Examiner therefore states that Zucherman teaches an interspinous implant having a groove and “a tether 31 passed into openings on the side faces of the groove 26 (Figure 2).” (Page 5 of the Office Action). The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to “construct the device of Reiley et al. with a strap connected at the holes on the side of the grooves for attachment to a spinous process in view of Zucherman et al.” (Page 5 of the Office Action). The Examiner further states that “Substituting one known means of attachment [t]o a spinous process for another, would have been obvious to one skilled in the art.” (Page 5 of the Office Action).

Applicant respectfully traverses the rejections set forth by the Examiner, and submits that neither Biedermann nor Lutz, alone or in combination, discloses or suggests the systems for performing spine surgery as claimed.

Independent claim 15 recites an intervertebral implant for the lumbo-sacral joint including, among other things, a spacer adapted to fit between the fifth lumbar vertebra and the sacral vertebra, wherein the spacer includes a body having a top end face with a groove that

extends along a midplane of the spacer, and a bottom end face with a longitudinal housing that extends orthogonal to the groove. Independent claim 15 further recites that the implant includes a strap, wherein the groove has a first side and a second side with first and second openings, respectively, such that a first end of the strap is passed into the first opening and a second end of the strap is passed into the second opening. As recited in independent claim 15, the groove is adapted to receive the spinous process of the lumbar vertebra and the longitudinal housing is concave in order to receive and rest directly on a top portion of the convex sacral vertebra.

By contrast, Reiley is specifically directed to “protheses for replacing inferior and/or superior portions of natural facet joints. The protheses are desirably fixed to vertebral bodies following the surgical removal of the respective natural facet joint portions from the vertebral bodies” (Paragraph [0071]). The prosthetic articulated joint of Reiley includes a “cephalad prosthesis 36 for replacement of the natural inferior half of a facet joint,” and “a caudal prosthesis 38 for replacement of the natural superior half of a facet joint” (Paragraph [0072]). The “cephalad prosthesis 36 is sized to extend across the laminae 20 of a vertebral body ... [and] comprises a chimney 42” (Paragraph [0079]). The chimney is configured to receive a spinous process of a vertebral body. The chimney “carries right and left arms 44 in association with the chimney 42. Each arm 44 carries an artificial facet joint structure 40” (Paragraph [0081]). Each arm carries at least one opening for receiving a fixation element, which can take the form of pedicle screws or nails. As shown in FIG. 16 of Reiley, the two protheses of Reiley specifically form an articulated joint by receiving a ball 68 in a groove 70. Hence, Reiley does not even disclose an intervertebral implant for the lumbo-sacral joint, let alone such an implant with the spacer body and strap as claimed.

Zucherman discloses systems and methods for relieving pain by implanting a device between adjacent spinous processes. The implant of Zucherman can include forked ends each defining a saddle that receives a spinous process. Alternatively, various forms of wedges are depicted in Zucherman, allowing for different shapes and sizes and configurations of implant to be received between two adjacent spinous processes. The Examiner points to Zucherman FIG. 2 as describing that the device can include a tether. However, Zucherman notes that “one of the

saddles 26 can be laterally pinned with pin 29 to one of the spinous processes and the other saddle can be loosely associated with the other spinous processes by using a tether 31 which either pierces or surrounds the other spinous process and then is attached to the saddle in order to position the saddle relative to the spinous process” (col. 4, lines 2-8). There is no disclosure or suggestion by Zucherman that such an implant can be used at the lumbo-sacral joint, nor is there disclosure or suggestion of a spacer body as claimed.

The U.S. Patent and Trademark Office (“PTO”) published new guidelines on October 10, 2007, for Examiners to use in performing an obviousness analysis based on the recent U.S. Supreme Court decision in *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). Fed. Reg. 72:195, 57526-57535 (Oct. 10, 2007). The PTO guidelines state that PTO personnel must make the underlying factual inquiries required by *Graham v. John Deere Co.*: (1) determine the scope and content of the prior art; (2) ascertain the differences between the claimed invention and the prior art; and (3) resolve the level of ordinary skill in the art. The PTO guidelines also set forth seven specific rationales for rejecting claims as obvious based upon those underlying factual inquiries, as well as the specific requirements that must be met to support a rejection under each rationale.

The Examiner’s basis for the instant rejection is that it would have been obvious to one of ordinary skill in the art at the time the invention was made to adapt the device of Reiley by substituting a strap or tether as shown in Zucherman for the fixation screws or nails disclosed in Reiley (See page 5 of the Office Action). The Examiner specifically states that “[s]ubstituting one known means of attachment [t]o a spinous process for another, would have been obvious to one skilled in the art.” (Page 5 of the Office Action). In view of this language, it seems that the obviousness rejection is based upon the rationale identified in the PTO guidelines as “B. Simple substitution of one known element for another to obtain predictable results.” Fed. Reg. 72:195 at 57534.

To support a rejection under this rationale, the PTO guidelines state that, upon resolution of the *Graham* factual inquiries, PTO personnel must articulate:

- “(1) a finding that the prior art contained a device (method, product, etc.) which differed from the claimed device by the substitution of some components (step, elements, etc.) with other components;
- (2) a finding that the substituted components and their functions were known in the art;
- (3) a finding that one of ordinary skill in the art could have substituted one known element for another, and the results of the substitution would have been predictable; and
- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.”

Id. The PTO guidelines further state that “if any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.” *Id.*

(1) A finding that the prior art contained a device which differed from the claimed device by the substitution of some components with other components

In the rejection of independent claim 15, the Examiner states that Reiley discloses an intervertebral implant including, among other things, a top end face including a groove, and a lower end face including a longitudinal housing extending orthogonally to the groove. Applicant disagrees. For example, Applicant respectfully submits that Reiley does not disclose or suggest, among other things, an implant having a longitudinal housing at the bottom end face of a spacer body, wherein the longitudinal housing extends orthogonal to a groove in the top end face of the body, and further where the longitudinal housing is concave to receive and rest directly on the convex sacral vertebra, as recited in claim 15. The intervertebral implant of independent claim 15 is configured to be received between the fifth lumbar vertebra L5 and the sacral vertebra S1, as shown in FIG. 1 and disclosed in paragraph [0030]. Lumbar vertebra L5 has a spinal process, whereas sacral vertebra S1 does not. As such, the top end of Applicant’s implant has a groove that receives the spinous process of vertebra L5, while the lower end of Applicant’s implant includes a concave longitudinal housing to receive and rest directly on a top portion of the convex sacral vertebra.

Reiley does not disclose or suggest such a configuration. Rather, Reiley specifies an artificial vertebral joint having two separate plate-like prostheses that cooperate to function as a joint. Each of these two prostheses is anchored to a respective vertebra using bone fixation screws or nails as shown in FIGS. 4-6 of Reiley. The Examiner argues on page 3 of the Office Action in reproduced FIG. 32, that the longitudinal housing is the lower portion of the cephalad prosthesis by pointing to concave surface 70. Applicant respectfully submits that concave surface 70 of Reiley is configured, not to receive and rest directly on a top portion of the convex sacral vertebra as recited in Applicant's claim 15, but rather to receive the ball shaped portion of the caudal prosthesis and by "employing generally complementary convex surfaces 70, forming hemisphere-like artificial facet joint structures that articulate with the socket-like ... structures" (Paragraph [0126]).

Applicant also respectfully submits that Zucherman likewise does not disclose or suggest an implant for a lumbo-sacral joint, including a spacer body having a concave longitudinal housing to receive and rest directly on a top portion of the convex sacral vertebra. Rather, Zucherman discloses various spine distraction implants and methods, all of which share the common feature of "use of an implant and method which distract the spinous process of adjacent vertebra" (col. 1, lines 30-31). As described herein above, Applicant's intervertebral implant is configured to be received between lumbar vertebra L5 and sacral vertebra S1 which does not have a spinous process as is well known in the art. Zucherman only contemplates spinal implants that are received between two adjacent processes. Therefore, Zucherman does not disclose or suggest an implant for use with the sacral vertebra, let alone an implant including a concave longitudinal housing at a bottom end face to receive and rest directly on a top portion of the convex sacral vertebra.

In view of the foregoing, Applicant respectfully submits that the prior art of record, alone or in combination, does not even disclose each and every element of the system recited in independent claim 15.

(2) A finding that the substituted components and their functions were known in the art

As detailed above, Applicant respectfully submits that the cited prior art does not disclose or suggest an intervertebral implant that includes a lower end having a longitudinal housing that is concave to receive and rest directly on a top portion of the convex sacral vertebra, let alone such a longitudinal housing on a bottom end face of a spacer implant and orthogonal to a groove on the top end face of the spacer implant.

Applicant respectfully submits that at least the concave longitudinal housing configured as claimed for direct receipt of the sacral vertebra was not known in the art, nor was its corresponding function.

(3) A finding that one of ordinary skill in the art could have substituted one known element for another, and the results of the substitution would have been predictable

Applicant submits that the combination of Reiley and Zucherman would not have rendered predictable results in accordance with *KSR International Co. v. Teleflex Inc.*, 127 U.S. 1727, L.Ed.2d 705. Under *KSR*, the combination of prior art elements is required to provide predictable results to support a finding of obviousness. Indeed, even if all of the claim features were disclosed in Reiley and Zucherman if combined, there is still no suggestion or indication that combining the references would yield predictable results. As discussed above, Reiley is directed to a prostheses for replacing inferior and/or superior portions of natural facet joints in which the prostheses are fixed to vertebral bodies following the surgical removal of the respective natural facet joint portions from the vertebral bodies. Zucherman is directed to various spine distraction implants and methods, all of which specify the use of an implant and method which distract the spinous process of adjacent vertebra. Neither Reiley nor Zucherman discloses or suggests an implant configured for receiving the convex sacral vertebra.

Assuming for the sake of argument that such a feature would have been obvious, Applicant respectfully submits that one of skill in the art still would not have substituted the strap of Zucherman for the bone fixation screws of Reiley as suggested by the Examiner. Based upon the disclosure, it is apparant that each of the prostheses of Reiley must be rigidly affixed to its

vertebra in place of removed bone tissue in order to provide sufficient support to operate as an artificial joint. Even if one could attach the strap of Zucherman to the screw holes of Reiley as suggested by the Examiner, and Applicant submits that such is not a simple substitution, the prosthesis would not have the desired rigid fixation required to operate as an artificial joint as contemplated by Reiley.

In view of the above, Applicant respectfully submits that it would not have been obvious to a person having ordinary skill in the art to combine the disclosures of Reiley and Zucherman in such a way as to contemplate the structures as claimed, nor would the benefits or results have been predictable.

Additionally, Applicant respectfully submits that the use of strap of Zucherman in place of the bone fixation screws of Reiley directly contradicts the intent and purpose of Reiley, because the strap will not function to rigidly affix the prostheses to vertebrae to allow for an artificial joint. *See* MPEP § 2143.01 (“The Proposed Modification Cannot Render The Prior Art Unsatisfactory For Its Intended Purpose”).

For at least these reasons, Applicant submits that the Examiner has not met the burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103(a). Independent claim 15 is therefore allowable over the prior art of record.

Similarly, claims 16-30 also are allowable at least for depending on the allowable independent claim. Furthermore, each of these dependent claims is allowable for reciting additional features not disclosed by the prior art relied upon by the Examiner. For example, dependent claim 16 recites specific features of the first the spacer presenting first and second opposite side faces into which the groove opens out and wherein the spacer includes a tab of width narrower than the width of the body in the direction orthogonal to the midplane of the spacer. No such configuration is disclosed or suggested in the prior art. Claim 17 recites the additional feature of a section of the housing in the midplane being generally U-shaped. Claim 18 recites the additional feature of the midplane of the housing being inclined relative to the midplane defined by the bottom of the groove. Claim 19 recites the additional feature of the inside face of the tab being convex. Claims 20 and 21 recite the additional feature of a zone of

the inside face of the tab being inclined. Claims 22 and 23 recite the additional feature of a portion of the second side of the extension being inclined. Claim 24 recites the additional feature of a notch being formed in the extension facing the tab. Claim 26 recites the additional feature of the spacer including first and second fastener means. Claims 27 and 28 recite additional features of the fastener means being a strap. Claims 29 and 30 recite additional features of methods of limiting displacement of the fifth lumbar vertebra relative to the sacral vertebra. These additional features are not disclosed or suggested by the prior art of record in a structure or article as claimed.

Applicant therefore respectfully submits that independent claim 15 and dependent claims 16-24, and 26-30 depending therefrom, are in condition for allowance.

Formal Request for Interview

Applicant submits that the present application is in condition for allowance at least for the reasons set forth herein. If the present application is not considered to be in condition for allowance by the Examiner, Applicant requests an interview with the Examiner prior to the next Office Action to discuss the present application and the prior art of record. Applicant's Attorney Daniel J. Hulseberg may be reached at telephone number (212) 408-2594 to schedule a mutually convenient date and time and to provide assistance or additional information as required.

CONCLUSION

On the basis of the foregoing Remarks, Applicant submits that this Amendment After Final does not raise new issues for consideration or necessitate the undertaking of any additional search of the art by the Examiner. This Amendment After Final should therefore allow for immediate action by the Examiner.

Applicant also submits that entry of this Amendment After Final and the accompanying remarks would place the present application in better form for appeal, should the Examiner dispute the patentability of any of the pending claims.

On the basis of the foregoing Remarks, Applicant respectfully submits that the pending claims of the present application are allowable over the prior art of record. Applicant thus respectfully requests that this Amendment After Final be entered by the Examiner and the rejections of the pending claims be withdrawn.

The Examiner is invited to contact the undersigned at (212) 408-2500 if any additional information or assistance is required.

Applicant authorizes the Commissioner to charge any fees (including fees for extra claims) and/or credit any overpayments associated with this paper to Baker Botts L.L.P. Deposit Account No. 02-4377, Ref. No. 003168.0709. Further, if a fee is required for an extension of time under 37 C.F.R. § 1.136 not provided for above, Applicant requests such extension and authorizes the charging of the extension fee to Baker Botts L.L.P. Deposit Account No. 02-4377, Ref. No. 003168.0709.

Respectfully submitted,

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